



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Ms. Beth A. Roberts
Regulatory Specialist
Premier Laser Systems, Inc.
3 Morgan
Irvine, California 92618

Re: K993285
Trade Name: Aurora™ SL Diode Laser System
Regulatory Class: II
Product Code: GEX
Dated: September 28, 1999
Received: September 30, 1999

Dear Ms. Roberts:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

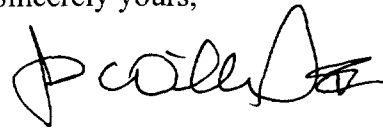
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Dillard III", with a stylized flourish at the end.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K993285

Device Name: Aurora™ SL Diode Laser System

Indications for Use:

EAR, NOSE AND THROAT AND ORAL SURGERY: *Hemostasis, incision, excision, ablation and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity. Examples:*

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in-situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of Herpes Simplex I and II
- Pulpotomy and pulpotomy as an adjunct to root canal therapy
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)

ARTHROSCOPY: *Hemostasis, incision, excision, vaporization and ablation of joint tissues during arthroscopic surgery. Examples:*

- Meniscectomy
- Synovectomy
- Chondromalacia

GASTROENTEROLOGY: *Hemostasis, excision and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy. Examples:*

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

GENERAL SURGERY, DERMATOLOGY & PLASTIC SURGERY, AND PODIATRY: *excision, ablation, and vaporization of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissues, and dermabrasion. Examples:*

- Matrixectomy
- Excision of neuromas
- Excision of periungual & subungual warts
- Port wine stain removal
- Excision of plantar warts
- Excision of keloids
- Cholecystectomy
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy


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Prescription Use X
(Per 21 CFR 801.109)

- Appendectomy
- Debridement of decubitus ulcer
- Hepatobiliary
- Mastectomy
- Dermabrasion
- Vaporization & hemostasis of capillary hemangioma
- Excision, vaporization & hemostasis of abdominal tumors
- Excision, vaporization & hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorrhaphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs

GI/GU: *Excision, vaporization, and hemostasis of abdominal and rectal tissues.*

Examples:

- Hemorrhoidectomy
- Excision, vaporization and hemostasis of rectal pathology
- Excision, vaporization, and hemostasis of abdominal tumors

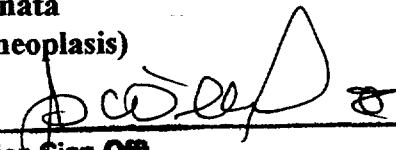
GYNECOLOGY: *ablation, excision, hemostasis and vaporization of tissue.*

Examples:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of CIN (cervical intraepithelial neoplasia)
- Cervical conization
- Menorrhagia

NEUROSURGERY:

- Hemostasis
- Hemostasis for myangioma


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OPHTHALMOLOGY:

- Incision, excision and vaporization of tissue surrounding the eye and orbit
- Photocoagulation of the retina

PULMONARY SURGERY: *Hemostasis, vaporization, and excision of tissue.*

Examples:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction

UROLOGY: *Hemostasis, vaporization and excision of tissues. Examples:*

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction

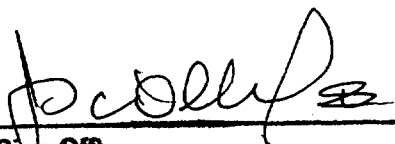
Prescription Use X
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- **Excision and vaporization of condyloma**
- **Lesions of external genitalia**

NOTE:

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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Prescription Use X
(Per 21 CFR 801.109)

Or

Over-The-Counter Use _____